## ARTICLE 3. WHOLESALE LEGEND DRUGS

### Rule 1. Definitions

**856 IAC 3-1-1 Definitions**
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. All terms which are defined in IC 25-26-14 shall have the same meanings as they are so defined when used in this article. *(Indiana Board of Pharmacy; 856 IAC 3-1-1; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2460; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

### Rule 2. Licensing and Operational Requirements

**856 IAC 3-2-1 Persons required to register**
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. (a) Every person who engages in wholesale drug distribution is required to obtain a wholesale drug distributor license as required by IC 25-26-14. Only persons actually engaged in such activities are required to obtain a license; related or affiliated persons who are not engaged in such activities are not required to be licensed. For example, a stockholder or parent corporation of a corporation distributing legend drugs is not required to obtain a license.

(b) A separate license is required for each facility directly or indirectly owned or operated by the same person in Indiana.

(c) For the purpose of enforcement of the licensing requirement, "facility" means one (1) building or two (2) or more buildings in close geographic proximity to each other, such as a campus. A facility shall be identified by the wholesale drug distributor as constituting a single business operation. *(Indiana Board of Pharmacy; 856 IAC 3-2-1; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2460; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

**856 IAC 3-2-2 Fees**
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 2. (a) The fee for original licensure and biennial renewal shall be one hundred dollars ($100) for in-state applicants. The fee for original licensure and biennial renewal shall be one hundred dollars ($100) for out-of-state applicants.

(b) Licensure fees shall be paid at the time when the application for licensure or renewal of a license is filed. *(Indiana Board of Pharmacy; 856 IAC 3-2-2; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3107; readopted filed Oct 17, 2001, 3:30 p.m.: 25 IR 941)*

**856 IAC 3-2-3 Application forms; renewal forms**
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 3. (a) Applications for licensure may be obtained by writing to the Indiana Board of Pharmacy, Health Professions Bureau, 402 West Washington Street, Room 041, Indianapolis, Indiana 46204.

(b) Wholesale drug distributor licenses shall expire on September 30th of each even-numbered year. Applications for renewal shall be mailed to the licensee. *(Indiana Board of Pharmacy; 856 IAC 3-2-3; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

**856 IAC 3-2-4 Inspection and review of application**
Authority: IC 25-26-14-13
Affected: IC 25-26-14-17; IC 25-26-14-19

Sec. 4. The board may inspect, or cause to be inspected, the establishment of an applicant or licensee pursuant to IC 25-26-14-19. The board shall review the application for licensure and other information regarding an applicant to determine whether the applicable standards of IC 25-26-14-17 have been met by the applicant. *(Indiana Board of Pharmacy; 856 IAC 3-2-4; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

**856 IAC 3-2-5 Wholesale drug distributor license**

Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 5. (a) The board shall issue a wholesale drug distributor license to applicants that qualify under IC 25-26-14.

(b) The wholesale drug distributor license shall contain the name, address, and license number of the licensee, the amount of fee paid, and the expiration date of the license. The licensee shall maintain the wholesale drug distributor license in a readily retrievable manner and shall permit inspection of the license by any official, agent, or employee of the board. *(Indiana Board of Pharmacy; 856 IAC 3-2-5; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

**856 IAC 3-2-6 Termination of licensure; transfer of license**

Authority: IC 25-26-14-13
Affected: IC 25-26-14-14; IC 25-26-14-15

Sec. 6. (a) The license of any person shall terminate if and when such person dies or ceases legal existence. Any licensee who ceases legal existence or discontinues business shall notify the board within ten (10) days of such fact in writing.

(b) No license or any authority conferred thereby shall be assigned or otherwise transferred except to the extent allowed by IC 25-26-14-15, and then only pursuant to the written consent of the board. *(Indiana Board of Pharmacy; 856 IAC 3-2-6; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

**856 IAC 3-2-7 Reciprocity**

Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 7. (a) An out-of-state wholesale drug distributor may obtain a license on the basis of reciprocity after payment of the licensure fee provided in section 2 of this rule and upon a demonstration to the board that the distributor qualifies under IC 25-26-14-14(f).

(b) A person who possesses one (1) or more wholesale drug distributor licenses for facilities located in Indiana shall not be required to obtain a license for facilities located outside of Indiana. *(Indiana Board of Pharmacy; 856 IAC 3-2-7; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

**856 IAC 3-2-8 Minimum conditions for licensure, renewal, and operations**

Authority: IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 8. As a condition for receipt, renewal, and retention of a license, the following minimum requirements for the storage and handling of legend drugs, and for establishment and maintenance of legend drug distribution records, by wholesale drug distributors, their officers, agents, representatives, and employees are provided:

(1) All facilities at which legend drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(A) be of suitable size and construction to facilitate cleaning maintenance and proper operations;

(B) have storage areas designed to provide sufficient lighting, ventilation, temperature, humidity control, sanitation, working space, equipment, and security measures to assure safe and secure operation of the installation;

(C) have a quarantine area for storage of legend drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in outer or secondary sealed containers that have been opened;

(D) be maintained in a clean and orderly condition; and

(E) be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Provide security as follows:

(A) All facilities used for wholesale drug distribution shall be secure from unauthorized entry. To this end, licensees who handle and store controlled substances listed in Schedule II, Schedule III, Schedule IV, and Schedule V shall assure that their facilities meet the requirements of 856 IAC 2. In addition, facilities which handle or store controlled substances also shall meet the requirements of item (v). All other licensees shall meet the following requirements:

(i) Nonscheduled legend drugs shall, at a minimum, be stored in a building of substantial construction, with walls, roof, doors, and windows made or covered by materials which render unauthorized access difficult.

(ii) All doors providing access to such buildings shall, at a minimum, be constructed of a heavy wooden core covered by a steel plate or jacket on their outer surface, or be of equivalent construction. Primary access doors shall be equipped with a five (5) pin tumbler dead bolt lock at a minimum. Secondary access doors may be secured from the inside by means of a crossbar during periods when the facility is not in operation.

(iii) All ground floor windows shall be equipped with window locks.

(iv) Facility security systems shall include a central alarm or comparable intrusion detection system which will disclose attempts at unauthorized entry during hours when the facility is closed.

(v) The outside perimeter of these facilities shall be illuminated to a degree sufficient to disclose the presence of an unauthorized person or vehicle adjacent to the exterior surfaces of the building during hours of darkness.

(vi) Licensees of these facilities shall establish and practice measures of personnel control which will assure that only those persons authorized by the management shall have access to areas of the facility wherein legend drugs are handled or stored. In addition, procedures also shall be followed which control the access of personnel authorized to enter the facility on a temporary basis to perform necessary maintenance or for other useful purposes.

(vii) Whenever practicable, facilities shall be protected, additionally, by arrangement with local law enforcement agencies or central guard forces for employment of a quick reaction force in event of forcible entry or other occurrences beyond facility control.

(viii) The security system also shall provide protection against theft or diversion which is facilitated or hidden by tampering with computer systems or electronic records used by licensee.

(B) Facilities which include administrative offices in the same building wherein drugs are handled or stored are not required to comply with the requirements under clause (A)(i), (A)(ii), or (A)(iii) for the office portion of the building; provided, that any door or window connecting the offices with the storage areas of the building meets the requirements of clause (A)(i), (A)(ii), or (A)(iii).

(3) All legend drugs shall be stored at temperatures and under conditions in accordance with manufacturers' requirements, if any, in the labeling of such drugs:

(A) if no storage requirements are established for a legend drug, the drug may be held at a temperature maintained thermostatically between fifty-nine degrees Fahrenheit (59°F) and eighty-six degrees Fahrenheit (86°F) to help ensure that its identity, strength, quality, and purity are not adversely affected;

(B) appropriate manual, electro-mechanical, or electronic temperature and humidity recording equipment, devices, and logs shall be utilized to document proper storage of legend drugs; and

(C) the record keeping requirements under subdivision (6) shall be followed for all incoming and outgoing legend drugs.

(4) Examination of materials shall be as follows:

(A) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated legend drugs or legend drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal damage or tampering that would suggest possible contamination or other damage to the contents.

(B) Each outgoing shipment shall be carefully inspected for identity of the legend drug products and to ensure that there is no delivery of legend drug products that have been damaged in storage or held under improper conditions.

(C) The record keeping requirements under subdivision (6) shall be followed for all incoming and outgoing legend drugs.

(5) Returned, damaged, and outdated prescription drugs shall be handled as follows:

(A) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be held in a quarantine

area and physically separated from other legend drugs until they are destroyed or returned to their manufacturer or other agency of origin.

(B) Any legend drugs which have sealed outer or secondary containers that have been opened or used shall be identified as such and shall be quarantined and physically separated from other legend drugs until they are either destroyed or returned to the supplier.

(C) If the conditions or circumstances under which a legend drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be properly destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not circumstances under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(D) The record keeping requirements in subdivision (6) shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated legend drugs.

(6) Record keeping shall be as follows:

(A) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. At a minimum, these records shall include the following information:

(i) The source of the drugs, including the name and principal address and telephone number of the seller or transferor, and the address of the location from which the drugs were shipped.

(ii) The identity and quantity of the drugs received, distributed, or disposed of.

(iii) The dates of receipt and distribution or other disposition of the drugs.

(iv) The identity, principal address, and telephone number of recipients of the drugs.

(B) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials, including the board or its agents for a period of two (2) years following disposition of the drugs.

(C) Records described in this section which are kept at the inspection site, or which can be retrieved immediately by computer or other electronic means, shall be made available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency, including the board or its agents.

(7) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of legend drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(A) A procedure whereby the oldest approved stock of a legend drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and necessary.

(B) A procedure to be followed for handling recalls and withdrawals of legend drugs. Such procedures shall be adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;

(ii) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health and safety by replacement of existing merchandise with an improved product or new package design.

(C) A procedure to ensure that their facility is prepared to react to crises caused by natural disasters or catastrophic events in a manner which will limit losses through looting, theft, or burglary as much as possible under circumstances existing at the time.

(D) A procedure to ensure that any outdated legend drugs will be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of the outdated

legend drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs concerned.

(E) A procedure to be followed in instances wherein thefts or losses of legend drugs are established, which will assure complete reporting of the incident to the board, within ten (10) days of when it is established, and to other law enforcement agencies as required by law.

(8) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug reception, storage, handling, and distribution including a description of their duties and a summary of their qualifications.

(9) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. To this end, distributors shall:

(A) permit the board or its agents and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures to the extent authorized by law; and

(B) wholesale drug distributors who deal in controlled substances shall register with the Indiana controlled substance advisory committee and with the Drug Enforcement Administration and shall comply with all applicable federal, state, and local laws and regulations.

(10) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations which pertain to the reprocessing or salvage of legend drug products.

*(Indiana Board of Pharmacy; 856 IAC 3-2-8; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

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